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The need for Legal and Ethical Frameworks for Artificial Intelligence in Artificial Reproduction Technology Practices in Africa: The Role of the African Union

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INTRODUCTION

The term Artificial intelligence (AI) was coined by Standford Professor John McCarthy at the Dartmouth conference in 1956. It refers to systems that display intelligent behaviour by analysing their environment and taking action – with some degree of autonomy – to achieve specific goals.[1] According to the Organisation for Economic Co-operation and Development, AI is a machine-based system that can, for a given set of human-defined objectives, make predictions, recommendations, or decisions influencing real or virtual environments.[2] From these definitions, it can be construed that AI systems are designed to operate with varying levels of autonomy and it leverages computers and machines to simulate and mimic human intelligence. AI is typically implemented as a system comprised of both software and hardware.[3] AI utilizes computational power, deep learning algorithms, and graphics processing units (GPU) produced by Nvidia' to process vast datasets and derive insights to emulate cognitive functions such as tackling language understanding, learning, logical reasoning, problem-solving, and/or

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[1] Article 4(a) of the European Parliament Resolution of 20 October 2020 with the recommendation to the Commission on a Framework of Ethical Aspects of Artificial Intelligence, Robotics and Related Technologies, The European Commission's 2018, Philip Boucher, "Artificial Intelligence: How does it work, why does it matter and what can we do about it?' June 2020 European Parliamentary Research Service https://www.europarl.europa.eu/RegData/etudes/STUD/2020/641547/EPRS_STU(2020)641547_EN.pdf

[2] Organisation for Economic Co-operation and Development, 'Recommendation of the Council on Artificial Intelligence' (2019) OECD Legal Instruments <https://legalinstruments.oecd.org/en/instruments/OECD-LEGAL-0449> accessed 5 January 2024

[3] Jakub Growiec, 'The Hardware-Software Model: A New Conceptual Framework of Production, R&D, and Growth with AI' (2019) KAE Working Papers < http://hdl.handle.net/20.500.12182/1120> accessed 5 January 2024

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decision-making[4]. Deep learning refers to a class of algorithms which are based on artificial neural networks optimized to work with unstructured data such as images, voice, videos and text.[5] While GPU is an electronic circuit which manipulates and modifies the memory for better image output.[6] Deep learning involves huge amounts of matrix multiplications and other operations which can be massively parallelized and thus done on GPUs.[7] AI uses such algorithms to learn how to complete tasks through many rounds of trial and error.[8]

AI portfolio also involves Natural Language Processing (NLP), Robotics, Machine Learning, and Cognitive Computing.[9] Machine Learning (ML) is a particularly successful AI application.[10] It identifies patterns between variables in a large dataset. Most ML approaches can be classified as supervised, unsupervised or reinforcement learning.[11] Supervised ML uses labelled training data to develop models in which target results (such as a diagnosis) are known. In contrast, unsupervised ML recognizes patterns or aggregations that occur within data without requiring labelled data.[12] Reinforcement ML uses a system with reward and punishment methods to form a solution strategy to solve some problems.[13]

Presently, the adoption and use of AI is rapidly increasing. AI is becoming more widely adopted and integrated into many aspects of daily life, including commerce, health, education, communication, and public service, holding significant impact in almost all areas where human intelligence is involved.[14] AI can be used by businesses and institutions to optimize operations, promote innovations, and empower and supplement staff.[15] For instance, AI models can run in cars to avoid accidents,[16] in smartphones to perform various tasks,[17] in banks to manage investments and loans,[18] and in law enforcement to help officials recover evidence and make law enforcement easier. In the same vein, AI is used in hospitals to aid doctors. AI can effectively analyze and provide valuable insights

[4] Ziyad Saleh, 'Artificial Intelligence Definition, Ethics and Standards' (2019) Research Gate <https://www.researchgate.net/publication/332548325_Artificial_Intelligence_Definition_Ethics_and_Standards > accessed 5 January 2024

[5] Vijay Kotu and Bala Deshpande, *Data Science Concepts and Practice* (Elsevier Inc, Second Edition, Morgan Kaufmann 2019)

[6] (Chapter 1 - Parallel Computing, Graphics Processing Unit (GPU) and New Hardware for Deep Learning in Computational Intelligence Research) M Madiajagan and S Sridhar, *Raj Deep Learning and Parallel Computing Environment for Bioengineering Systems* (Academic Press,2019) https://doi.org/10.1016/B978-0-12-816718-2.00008-7

[7] ibid

[8] Xuli Tang, Xin Li, Ying Ding, Min Song and Yi Bu, 'The Pace of Artificial Intelligence Innovations: Speed, Talent and Trial-and-Error' (2020) 14(4) Journal of Informetric

[9] AC Chang, 'Intelligence-based medicine: Artificial intelligence and human cognition in clinical medicine and healthcare' (2020) Academic Press

[10] Vasilija Rolfes, Uta Bittner, Helene Gerhards, Dr Ja-Steffen Krussel, Prof. Tanja Fehm, Prof Robert Ranisch, and Prof Heiner Fangerau, 'Artificial Intelligence in Reproductive Medicine – An Ethical Perspective' (2023) 8(1) Geburtshilfe Frauenheikd' 108-115

[11] Zoumana Keita, 'Classification in Machine Learning: An Introduction' (Data Camp, September 2022) < https://www.datacamp.com/blog/classification-machine-learning> accessed 5 January 2024

[12] Rolfes, Bittner, Gerhards, Dr Krussel, Prof. Fehm, Prof Ranisch, and Fangerau, 'Artificial Intelligence in Reproductive Medicine'(n10)

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[15] W Schoeman, R Moore, Y Seedat and J Chen 'Artificial Intelligence is South Africa ready' (2021) Responsible AI in Africa https://link.springer.com/chapter/10.1007/978-3-031-08215-3_5#ref-CR52

[16] Stuart Rauch, 'AI in the Automotive Industry: A 2024 Outlook' (Simpli Learn, 28 November 2023) < https://www.simplilearn.com/ai-in-automative-article> accessed 5 January 2024

[17] MA Ahmed, EE Saket and Ali Alshish, 'Mobile Phones and Use of Artificial Intelligence with Android Applications' (2021) 51(6) PENSEE 1275

[18] O Oriji, MA Shonibare, RE Daraojimba, O Abitoye and C Daraojimba, 'Financial Technology Evolution in Africa: A Comprehensive Review of Legal Frameworks and Implications for Ai-Driven Financial Services' (2023) 5(12) International Journal of Management & Entrepreneurship Research 929-951

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from the vast amount of data included in electronic medical records and hospital data.[19] AI could facilitate faster, more efficient health system calculations of cost-benefit ratios and help in decision-making.

In reproductive medicine, reproductive specialists can determine the most effective treatment for each patient's unique infertility by integrating AI: ML and DL.[20] Infertility is a disease of the male or female reproductive system that is defined by the failure to achieve pregnancy after 12 months or more of regular unprotected intercourse.[21] Assisted Reproductive Technology, also known as Artificial Reproductive Technology (ART) encompasses a range of medical interventions aimed at overcoming infertility.[22] These interventions include in vitro fertilization (IVF), intrauterine insemination, cryopreservation of oocytes and embryos, preimplantation genetic diagnostics, and other diagnostic procedures.[23] Despite significant advancements, there are still several challenges that need to be addressed in this field. For instance, there is a lack of reliable methods for assessing the quality of oocytes, sperm, and embryos.[24] In Germany, the success of giving birth after a fresh embryo transfer following IVF or intracytoplasmic sperm injection is approximately 24%.[25] A study conducted in a tertiary hospital in southwest Nigeria reported a pregnancy rate of 23.7% per ART cycle, with a delivery rate of 49.7% for women who achieved pregnancy.[26]

These challenges and recurrent ART failures have led to the development of AI models in ART. It is justified by the suffering of men and women of reproductive age who wish to have children but are unable to conceive. This global issue affects up to 186 million people and 48.5 million couples worldwide.[27] The integration of AI in ART has the potential to improve infertility diagnosis and ART outcomes. By taking large amounts of data and combining them to obtain meaningful results, AI can estimate pregnancy and/or birth rates.[28] In ART, AI can be utilised to improve the selection and prediction of sperm cells, oocytes, and embryos and to generate better predictive models for IVF.[29] AI also has tremendous implications in the assessment of male infertility, with computerized semen analysis methods now in use and a wide range of prospective AI-based applications in environment and lifestyle, assessments to predict semen quality can be more accurate.[30] Furthermore, significant progress has been made in harnessing AI in cases of idiopathic infertility, to improve the stratification of infertile couples based on their biological and clinical signatures.[31] In the African context, where reproductive health has significant cultural and social implications, the incorporation of cutting-edge technologies like AI into ART

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[20] M Fralick, E Colak and M Mamdani, 'Machine Learning in Medicine' (2019) 380(26) England Journal of Medicine 2588-2589

[21] World Health Organisation, Infertility, 3 April 2023 https://www.who.int/news-room/fact-sheets/detail/infertility

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[27] The Lancet Global Health, 'Infertility-why the silence?' (2022) 10(6) The Lancet Global Health < https://doi.org/10.1016/S2214-109X(22)00215-7> accessed 5 January 2024

[28] Medenica, Zivanovic, Batkoska, Marinelli, Giuseppe, Perino, Gullo and Zaami 'Artificial Intelligence in the Treatment of Infertility' (n24)

[29] Rolfes, Bittner, Gerhards, Dr Krussel, Prof. Fehm, Prof Ranisch, and Fangerau, 'Artificial Intelligence in Reproductive Medicine' (n10)

[30] Medenica, Zivanovic, Batkoska, Marinelli, Giuseppe, Perino, Gullo and Zaami 'Artificial Intelligence in the Treatment of Infertility' (n24)

[31] ibid

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practices can transform family planning and reproductive healthcare outcomes.[32] However, research into the application of artificial intelligence in reproductive medicine and ART is still in its early stages, necessitating the development of an ethical standard and a regulatory framework. The transformational influence that AI in ART might have on individuals and communities emphasizes the need to address the ethical implications of AI in ART in Africa. The promise of improved fertility treatment success rates and individualized reproductive healthcare must be evaluated against possible risks such as data privacy issues, fair access to new technologies, and the potential commercialization of reproductive processes.[33]

In this dynamic landscape, the absence of a defined legal and ethical framework governing the use of AI in ART creates a gap that requires urgent attention. The consequences of this include the risk of privacy breaches in sensitive medical data and the possible exacerbation of existing disparities in healthcare access. The purpose of this article is to explore the need to establish a robust legal and ethical framework to guide the integration of AI into ART practices within Africa, with a specific focus on the influential role that the African Union can play in shaping this framework.

AI INTEGRATION IN ART PRACTICES ACROSS AFRICAN NATIONS

Infertility, maternal, reproductive and health are critical issues in Africa that have far-reaching implications for the continent's development.[34] In some places in sub-Saharan Africa, it seems that up to 30% of the couples are infertile and the social stigma of childlessness still leads to isolation and abandonment.[35] This may result in polygamy, physical and psychological violence, and even suicide. As a result, accessible diagnostic treatments and inexpensive ART are required. The effectiveness and accessibility of ART in Africa vary by region. For example, a clinical pregnancy rate of 16.3% per embryo transfer was reported in South Africa using a low-cost technique, demonstrating a decent level of efficacy. Despite major advances in ART in recent years, Africa continues to confront several obstacles in these areas. The availability and accessibility of ART in Africa are still limited. The World Report on ART stated that data from Africa represented only 1% of global ART activity, indicating challenge in access to ART across the continent.[36] Consequently, it stands to reason that there may be several ways in which ART may be enhanced through the integration of AI. AI has shown great promise in reproductive health and is permeating the African social system through a variety of applications. The goal is to enhance the treatment and prognosis of infertile individuals, as well as ART accessibility, by collecting and integrating vast amounts of data to obtain meaningful results.[37]

Complex AI algorithms are increasingly being used in Africa to examine enormous amounts of data to improve ART diagnosis, prediction, and prevention.[38] Among these AI algorithms, supervised machine learning is a commonly used technique in ART to classify data based on provided information. It involves using previously supplied cases to predict the future of those instances, such as identifying the optimal morpho kinetic parameters of embryos, establishing cost efficiency in human oocyte cryopreservation, forecasting IVF outcomes, and classifying sperm cells.[39] Although unsupervised ML is not fully used in ART, it is usually used for image processing and principal component analysis. The usage of this is beneficial in pregnancy predictions based on the quality of oocytes with a success rate of roughly 60%.[40] AI software can spot sperm and identify DNA damage in

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[32] NB Chimbatata and C Malimba, 'Infertility in Sub-Saharan Africa: a Woman's Issue for How Long? A Qualitative Review of Literature' (2016) Mzuzu University Digital Repository <http://dx.doi.org/10.4236/jss.2016.48012 > accessed 5 January 2024

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[36] W Ombelet and J Onofre, 'IVF in Africa: What is it all about?' (2019) 11(1) Facts, Views and Vision in ObGyn 65-76

[37] Rolfes, Bittner, Gerhards, Dr Krussel, Prof. Fehm, Prof Ranisch, and Fangerau, 'Artificial Intelligence in Reproductive Medicine' (n10)

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[40] TO Togunwa, AO Babatunde and KR Abdullah, 'Deep Hybrid Model for Maternal Health Risk Classification in Pregnancy: Synergy of ANN and Random Forest' (2023) 6 Sec. Medicine and Public Health <https://doi.org/10.3389/frai.2023.1213436> accessed 6 January 2024

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sperm samples collected from severely infertile men 1,000 times faster than a highly trained pair of eyes.[41] In Uganda, machine learning algorithms have been developed to predict the probability of miscarriages among women seeking antenatal care, while identifying the major factors that influence a pregnancy ending in a miscarriage.[42]

AI-based methods can save time, eliminate subjectivity, and reduce inter and intra-observer differences to obtain more objective and precise results. In addition, AI can make diagnostic work-up and treatment through ART, including IVF in Africa more affordable. These include; simplified IVF culture systems; a ML model has been developed to predict a successful live birth through 30 IVF clinal features[43]; The initiative of the African Network and Registry for Assisted Reproductive Technology to register all IVF cycles in Africa providing more data sets for AI models. [44]

For male reproductive treatment using ART, in about one-third of men, the cause of their infertility cannot be identified through standard methods. Many ongoing research projects are exploring the use of AI analysis such as automated smartphone-based semen analyses.[45] A research team has developed two specific artificial neural networks using data-mining methods to predict human sperm concentrations and motility based on environmental factors and men's lifestyles.[46] In a study published in 2019, researchers from Cornell University trained a deep-learning algorithm from Google to recognize embryos with high, moderate, or low development potential, based on the probability of their successful implantation after intrauterine.[47]

Although AI has made significant progress in many sectors, it still faces significant problems in making exact predictions in other areas. Furthermore, a lack of infrastructure, both in terms of technology resources and experienced staff, is a key impediment to the broad use of AI.[48] The African health landscape's complexity and limited resources must be considered. AI progress must not be limited to serving the demands of the industrialized world, where the majority of research is conducted. With the exception of a few countries (such as South Africa, Nigeria, Ethiopia, Kenya, and Ghana), mainstream adoption of AI applications in Africa is still a long way off. [49] The critical variables required for technology adoption are tragically absent in much of Africa, and many African nations still lack the requisite infrastructure, governance, data ecology, STEM education, and other AI-related aspects. To drastically enhance ART practices in Africa, important issues such as the digital gap in ART infrastructure and shortages of reproductive specialists and AI expertise must be addressed, since these could impede the adoption of AI-driven ART.

Data is used to train algorithms. However, the way data is collected and used can potentially introduce biases, and user-generated data can perpetuate these biases. Therefore, it is crucial to ensure that algorithms are developed and used ethically, without any unjust biases. In Africa, it has been reported that there is a shortage of data and that the data that is collected may not accurately reflect the African experience. This suggests that algorithms developed using this data may not be correctly adapted to the local population. To ensure that AI is adopted

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[41] Katherine Latham, 'How AI may be a Powerful Tool in Treating Male Infertility' *BBC* (UnitedKingdom, 7 September 2023) <https://www.bbc.com/news/business-66608073 > accessed 6 January 2024

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[48] Eve Ruwoko, 'Africa Needs Data Set Infrastructure to Benefit From AI' *University World News* (Africa, 12 April 2022) <https://www.universityworldnews.com/post.php?story=20220412075232969 >

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responsibly in Africa, stakeholders need to openly discuss the ethical implications of AI and take necessary steps to mitigate any potential biases.

THE NEED FOR ETHICAL FRAMEWORK FOR AI IN ART

The use of AI in ART has immense promise for improving ART results; nevertheless, AI as a technology is still in its infancy, and it raises ethical concerns that must be addressed. AI systems in use today are only partially cognizant of human emotion, tone, expression, and social cues. There is still a long way to go before computers can fully act like humans.[50] The legal and ethical implications of using this sort of technology must be understood. The term ethics is derived from the Greek word ethos, which means "customs and habits". Ethics also refers to a code of conduct established and adopted by a group of persons (professional body), to guide or regulate the conduct of the members of that profession in the practice of their profession.[51] The medical profession has certainties of profession or standards of professional conduct. The Code of Medical & Dental Practice 2004, for example, set the accepted standard of practice for medical and dental practitioners in Nigeria. Though these ethical rules are not enforced by the state unless they are codified as law, a member may face other professional consequences. The four fundamental principles of ethics in the medical profession are patient autonomy, beneficence, nonmaleficence, and fairness.[52] AI systems and AI-powered medical robots can operate at least to some degree autonomously from human medical practitioners and to use ML to generate new, often unforeseen, analysis and prediction.[53] This poses challenges under the current framework of ethical guidelines applicable to health care in various African countries. The ethical challenges of importing these principles into the practices of AI-facilitated ART must be examined.

i. The Question of Consent and Transparency: The use of AI to make more accurate predictions in ART practices will be advantageous. Nonetheless, reproductive specialists must be able to process patient data conscientiously.[54] Certain ethical challenges include the increasing difficulty of ensuring informed consent on the part of the affected person, the potential risk of offspring and the difficulty of providing sufficient information.[55] Before implementing AI in ART practices, it is necessary to critically examine the quality and quantity of data used to address issues of transparency. The lack of transparency may also lessen patients' trust in relevant AI models. The two most fundamental characteristics of transparency are information accessibility and comprehension.[56] The functionality of algorithms is usually made purposefully difficult to achieve or so advanced that it is incomprehensible to a non-technically skilled clinical user. Because of the intricacy of the algorithms, educating patients is difficult, and treatment outcomes for specific individuals are unclear. Transparency and trust should be the ethical benchmarks. Women and couples who have had a lengthy and difficult experience of childlessness must be regarded as a vulnerable category. Providing well-considered information to the intended mother or intended parents will be critical in all future ART treatments on the use of AI in reproductive medicine. Furthermore, in this experimental arena, patents should allow patients to freely express their reproductive autonomy. Reproductive autonomy is pertinent. Individuals possess the capacity to make informed and independent decisions about their reproduction without any external influence.[57] Therefore, patients should have the ability to exercise their reproductive autonomy in AI models used in ART. This places an obligation on medical professionals to collect and record personal data such as age, weight, lifestyle information, and

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[53] Rolfes, Bittner, Gerhards, Dr Krussel, Prof. Fehm, Prof Ranisch, and Fangerau, 'Artificial Intelligence in Reproductive Medicine' (n10)

[54] A Kiseleva, D Kotzinos and P Hert, 'Transparency of AI in Healthcare as a Multilayered System of Accountabilities: between legal requirements and technical limitations' (2022) Frontiers in Artificial Intelligence https://www.frontiersin.org/articles/10.3389/frai.2022.879603/full accessed 5 January 2024

[55] Rolfes, Bittner, Gerhards, Dr Krussel, Prof. Fehm, Prof Ranisch, and Fangerau, 'Artificial Intelligence in Reproductive Medicine' (n10)

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more. This information can then be used to train algorithms in ART to help reproduction specialists explain the use of algorithms and decision support systems to their patients, and provide them with relevant information to make an informed decision.

ii. The Question of Safety: The primary priority and principle of any AI programming is always safety. There exist concerns that AI in ART may be a new source of inaccuracy. This is critical because mistakes can have severe consequences for the patient who is the victim of such an error.[58] Some AI methods are often considered "black-boxes," as they only attempt to elucidate the relationship between input and output variables based on the training set.[59] This leads to uncertainty regarding the generalization of new data not included in the previous data set. For instance, diagnoses that rely on subjective criteria can be challenging for AI models to predict treatment responses or long-term outcomes effectively. Likewise, rare diseases may pose similar challenges because there may not be enough data available to train models.[60] Thus, highly heterogeneous diseases, unique to each case, make it hard for AI to provide precise predictions for individuals with these conditions. Even when certain AI algorithms are used, there is no guarantee that an optimal solution can ultimately be achieved. Therefore, there should be broadly shared guiding standards to determine how to tune parameters within algorithms.

Reproduction specialists who use AI systems to support their diagnoses, prognoses, or treatment recommendations must ensure that these suggestions align with the current medical state of the art and their professional judgment. By doing so, they can honour their Hippocratic oath and act in the best interest of their patients.[61] It's important to note that AI decision-making systems cannot replace clinical judgment. Instead, they should be used as a tool to guide medical professionals in choosing the most individualized path to a successful outcome. To achieve this, the human decision-maker must be aware of the system's limitations, and the AI system must be designed to meet the requirements of the human decision-maker.

iii. The Question of Liability: AI is increasingly being used in healthcare and this has brought new players such as tech companies and programmers into the system. They play a crucial role in developing and testing ML systems for diagnoses and ART. However, the involvement of multiple actors in decision-making raises questions about who is ultimately responsible for any mistake that occurs.[62] If AI models in ART result in treatment errors or wrong diagnoses, it will create new challenges regarding responsibility. The use of AI can leave us without anyone to hold accountable for any damage caused. This problem is compounded by the fact that ML can operate like black boxes, with workings that are not visible to evaluators, reproduction specialists or patients.[63] At times, algorithms with high validity can no longer be explained, or the explanations would require significant effort or expense.[64] This lack of transparency makes it difficult to trace culpability back to the maker or operator, and it raises concerns about the safety consequences of using unverified or unvalidated AI in ART.

This is a challenging aspect of technology, and clinical rules of professional conduct do not allow for unaccountable behaviour. Reproductive Specialists and hospitals who employ it must be trained and bear ultimate responsibility for its usage. Verification and validation can assist a reproduction in appropriately accounting for their actions if they decide to use an AI. Before such AI is implemented, it must be logically and statistically/probabilistically established, tested, measured, and assessed for dependability, performance, safety, and ethical compliance.

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[58] OA Osoba and W Welser, 'An Intelligence in our Image: The Risk of Bias and Errors in Artificial Intelligence' (2017) Rands Corporation <https://www.rand.org/content/dam/rand/pubs/research_reports/RR1700/RR1744/RAND_RR1744.pdf>

[59] Rolfes, Bittner, Gerhards, Dr Krussel, Prof. Fehm, Prof Ranisch, and Fangerau, 'Artificial Intelligence in Reproductive Medicine' (n10)

[60] ibid

[61] H Askitopoulou and AN Vgontzas, 'The relevance of the Hippocratic Oath to the ethical and moral values of contemporary medicine. Part I: The Hippocratic Oath from antiquity to modern times' (2018) European Spine Journal < https://pubmed.ncbi.nlm.nih.gov/29080001/> accessed 6 January 2024

[62] Rolfes, Bittner, Gerhards, Dr Krussel, Prof. Fehm, Prof Ranisch, and Fangerau, 'Artificial Intelligence in Reproductive Medicine' (n10)

[63] Medenica, Zivanovic, Batkoska, Marinelli, Giuseppe, Perino, Gullo and Zaami 'Artificial Intelligence in the Treatment of Infertility' (n24)

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iv. While artificial intelligence can analyze historical data and discover patterns, it frequently fails to represent the complexities of human decision-making and the dynamic nature of socioeconomic issues.[65] Ethical issues for AI integration are critical in this multifaceted space. It is critical to understand the "implementation gap" in AI use in ART.

v. Questions of Fairness: This arises concerning resource allocation and cost reimbursement. It is necessary to confront the undesirable impact and social dynamics that may accompany the use of artificial intelligence in reproductive medicine.

THE NEED FOR LEGAL FRAMEWORKS FOR AI IN ART

The regulation of access to reproductive technology in Africa varies from country to country. For example, in Nigeria and other developing countries in sub-Saharan Africa, there is no official state regulation of ART, even though some centres in these countries have adopted AI models for their ART practices. [66] ART practitioners in these developing African countries voluntarily adhere to guidelines set by the American Society of Reproductive Medicine, British Human Fertilisation and Embryology Authority, or equivalent bodies in France or Germany. This voluntary adherence is due to the interaction and collaboration of ART centres in Africa with scientists in Europe, South Africa, Australia, and America. In Nigeria, the various ART centres are self-regulated, with no national body overseeing their affairs.[67]

The regulation of AI in ART is still in its early stages.[68] Currently, there are no well-established rules in place to address the legal and ethical issues that may arise from the use of AI in ART. The voluntary adherence to guidelines from different countries by various ART centres is not sufficient for regulating ART in Africa, especially with the integration of AI. It is important to note that Africa has a higher prevalence of infertility that can be solved by ART procedures and ART awareness is increasing in the country.[69] Therefore, all ART practitioners must come together and form a national body that can establish suitable standards of practice for African society and create a supervisory body for the centres.

The AI applications used in the field of ART must comply with national healthcare regulations specific to the African country they are being used. For instance, in South Africa, the National Health Act of 2003 must be followed. Other relevant legislation governing consumer products or services, personal information protection, access to personal information, and electronic transactions must also be applied. Even though several international organizations have developed guiding normative principles, they are largely similar. These principles emphasize the importance of respecting human rights and freedoms, transparency, fairness, security, beneficence, and accountability as core components of ethical AI development. [70]

African countries that are members of the United Nations Educational Scientific and Cultural Organisation (UNESCO) are expected to be guided by the recommendation on the Ethics of Artificial Intelligence adopted by UNESCO's General Conference at its 41st session on 24 November 2021 while developing national legislation and policy.[71]

The issue of liability presents a challenge from both an ethical and legal perspective. The traditional principles of fault-based liability for medical negligence may not be sufficient to compensate patients and users of new technologies and AI in ART who suffer harm where fault cannot be attributed to the reproductive specialist. [72] Some experts suggest developing a statutory framework for strict liability, along with mandatory insurance and appropriate forms of product liability for technology developers and manufacturers.

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[65] R William, 'Understanding and Avoiding AI Failures: A Practical Guide' (2021) MDPI https://www.mdpi.com accessed 6 January 2024

[66] AA Adewumi, 'The Need for Assisted Reproductive Technology Law in Nigeria' (2012) 2(1) Unib Law Journal 19-14

[67] Blessing Okoye and Chioma Nwabachili,'Rethinking A Legal Framework for Assisted Reproductive Technology' (2023) 4 International Journal of Law and Clinical Legal Education 1

[68] K Bærøe, A Miyata-Sturm, and E Henden, 'How to Achieve Trustworthy Artificial Intelligence for Health' 98 Bull World Health Organisation 257–262

[69] Dusty-Lee Donnelly, 'First Do No Harm: Legal Principles Regulating the Future of Artificial Intelligence In Health Care in South Africa' (2022) 25(1) Potchefstroom Electronic Law Journal

[70] Ibid

[71] UNESCO, Recommendation on the Ethics of Artificial Intelligence 2021 < https://unesdoc.unesco.org/ark:/48223/pf0000380455#:~:text=AI%20actors%20and%20Member%20States,law%2C%20in%20particular%20Member%20States' > accessed 6 January 2024

[72] Donnelly, 'First Do No harm' (n72)

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There is a fear that AI could potentially lead to data breaches due to the large amounts of data required for Machine Learning processes.[73] To integrate AI solutions into ART, a robust governance and legal framework is essential to ensure algorithmic transparency, privacy, and protection for everyone involved, as well as cybersecurity for associated vulnerabilities.[74] However, regulations around the lawful use of data are unevenly implemented in different countries and regions, especially when it comes to identifying patient identities. Existing and new legislation establishing ethical guidelines to prevent misuse of ART should be properly implemented to protect the well-being of parents and children born through these technologies.

To address the challenge of data risk, it is important to strengthen existing regulations on data protection as a first step towards AI regulation in Africa. This means implementing stringent penalties and sanctions for non-compliance, and ensuring that patients grant valid informed consent through suitable legal frameworks for data protection. Proper implementation and enforcement of data protection laws can guide the use of personal data such as biometrics, profiling tools, and automated processing. In addition, it is necessary to establish data regulatory bodies and agencies such as Kenya's Office of the Data Protection Commissioner and South Africa's Information Regulator, which have the power to enforce compliance and maintain institutional and political independence to avoid succumbing to political and private sector influence or intimidation.

The use of AI without human mediation raises concerns about vulnerabilities in cyber security, which can potentially jeopardize citizens' fundamental rights. These concerns are serious because they put key infrastructures at risk, endangering lives, human security and resource access. cyber security weaknesses can be a severe threat because they are usually hidden and only discovered after the damage is done.

THE ROLE OF AFRICAN UNION

This section discusses the African Union's (AU) commitment to promoting ethical principles and human rights throughout its history. It advocates for the AU to take a leadership role in developing a comprehensive framework that is uniquely tailored to the sociocultural fabric of Africa. The AU is an intergovernmental organization consisting of 55 member states located on the African continent. [75] It was established in 2001 to promote unity and solidarity among African states, spur economic development, and encourage international cooperation.[76] The AU replaced the Organization of African Unity (OAU).

The AU acknowledges the need for AI models in healthcare to be interpretable and rigorously controlled before they can become mainstream in clinical practice.[77] And encourage member countries to implement national-level frameworks and conventions like the Malabo Convention and the AU Data Policy Framework 2022. The Malabo Convention, also known as the AU Convention on Cyber Security and Personal Data Protection, is an essential tool for regulating aspects of AI, such as the automated processing of personal data.[78] While the AU Data Policy Framework, established in 2022, provides important principles to guide the development of national data policies.[79] As of 2023, thirty-five out of fifty-five countries have passed data protection legislation, twenty-five have established data protection authorities, eighteen of which are authorized to enforce compliance with data protection laws, however, nineteen have yet to pass legislation.[80]

Despite these achievements, the AU has not been able to marshal the weight of its continental policy-making mandates in a timely and effective manner. Member states tend to ignore their policy initiatives and look towards

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[73] JO Effoduh, UE Akpudo and JD Kong, 'Towards an Inclusive Data Governance Policy for the Use of Artificial Intelligence in Africa'(2023) SSRN < https://papers.ssrn.com/sol3/papers.cfm?abstract_id=4581619> accessed 6 January 2024

[74] Danielle Coleman, 'Digital colonialism: The 21st-century Scramble for Africa through the Extraction and Control of User Data and the Limitations of Data Protection Laws' (2018) 24 Mich. J. Race & L

[75] Thomas Kwasi Tieku, 'The African Union : Successes and Failures' (2019) Oxford Research Encyclopedia of Politics<https://www.researchgate.net/publication/343932679_The_African_Union_Successes_and_Failures#:~:text=Abstract,voice%20in%20the%20global%20system.> accessed 6 January 2024

[76] A Jen, *Peacebuilding in the African Union: Law, philosophy and practice*. (Cambridge, U.K.: 2012 Cambridge University Press)

[77] Eyong Ebai, 'Understanding Artificial Intelligence's (AI) Role in Accelerating Africa's Healthcare Momentum' (*Mea Market*, 21 September 2023) < https://www.mea-markets.com/understanding-artificial-intelligences-ai-role-in-accelerating-africas-healthcare-momentum/> accessed 6 January 2024

[78] Kinfe Yilma, 'African Union's Data Policy Framework and Data Protection in Africa'(2022) 5(3) Journal of Data Protection 209-215

[79] ibid

[80] Tech Hive Advisory 'Round Up of Data Protection Africa Report' (*Tech Hive Advisory*, January 4 2023) https://www.techhiveadvisory.africa/report/round-up-of-data-protection-africa accessed 6 January 2024

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Europe for international best practices. To reimagine the roles of AU's policy, pragmatic steps need to be taken. First, the AU may develop a coordinated program of work with institutions both within and outside the AU. An example of this is the draft of the Continental AI strategy put forward by the AU Specialized Technical Committee on Communication and ICT (STC-CICT) during the 5th Ordinary Session of the African Union Specialized Technical Committee on Communication and ICT in Addis Ababa, Ethiopia on November 23rd.[81] The approach aims to place Africa at the forefront of ethical and inclusive artificial intelligence for socioeconomic growth while mitigating any risks and negative consequences. However, the work planned for Africa's Digital Transformation under Agenda 2063 is still in the feasibility and scope stages[82] As a result, the African Union High-Level Panel on Emerging Technologies and the African Union Development Agency-NEPAD are holding a consultation conference with African AI specialists to complete the document.

Another important step is to launch or reconstitute a dedicated and well-resourced body with digital policy mandates, equivalent to the Executive Vice President of the European Commission for a Europe Fit for the Digital Age, responsible for digital affairs.[83] The AU should also appoint a commissioner responsible for digital affairs with broad policy mandates, including coordinating within the AU and supporting policy implementation in member states through various mechanisms, including capacity-building programs. Finally, the African Union Health Information Exchange Guidelines and Standards, which provide standards and guidelines to help develop and implement a digital health system on the African continent, should reflect the innovation of AI in health care, specifically ART, and set out a governance and legal framework for policies and standards while balancing privacy, security, and data sharing.[84] A revitalization of the judicial and quasi-judicial AU bodies is also important for the enforcement of digital policies.[85] To determine appropriate regulations, legal and ethical framework to be established, the adoption of AI regulatory Sand Boxes, where technologies are tested against existing regulations would be instrumental. Regulatory sandboxes can be utilized as test beds for future AI policies and regulations. The Smart Africa Blueprint on AI may be used by AU to establish its own AI plans. Such research and assessments can serve as the foundation for the creation of AI legislation and regulations that represent African values and norms while adhering to international standards such as the UNESCO guideline. Although AU policies arrive late, the organization is ideally poised to develop continental policies that are shaped not just by worldwide best practices but also by the distinctive socioeconomic and political circumstances of African nations.

CONCLUSION AND RECOMMENDATIONS

This research highlights the need to establish a legal and ethical framework for the use of AI in ART practices in Africa. The African Union can play a crucial role in ensuring that the integration of AI aligns with ethical standards and legal principles, promoting a responsible and inclusive approach to the transformative potential of artificial intelligence in ART.

The following recommendations are made:

1. AU Policymakers need to develop a detailed framework. The ultimate goal of such a blueprint should be to foster the development of AI in Africa to make the continent a leader in the development and implementation of innovative, ethically sustainable, and human-centred AI interventions in ART.
2. The AU should release ethical guidelines for trustworthy artificial intelligence, similar to the European Commission's noteworthy contribution in December 2019. In the report, the importance of AI in healthcare. The report emphasizes the critical nature of a resolution calling for the immediate creation of a legislative instrument governing robots and AI, capable of anticipating and adapting to any scientific breakthroughs such as ART expected in the medium term.
3. Furthermore, it is recommended that professional associations in African countries should create guidelines to regulate the practice of ART.

[81]African Union, 'Powering Africa's Digital Future: AU Ministerial Meeting Set to Ignite Digital Transformation in Africa' (*African Union Press Release*, 21 November 2023)

[82] Agenda 2063 seeks to transform Africa into the global powerhouse of the future through inclusive growth and sustainable development.

[83]UNED, 'Introduction to Digital Economy in the EU' (2020) UNED < https://blogs.uned.es/digitaleconomy/wp-content/uploads/sites/253/2020/12/Introduction-to-Digital-Economy-in-the-EU.pdf> accessed 6 January 2024

[84] African Centres for Disease Control and Prevention, 'The African Union Health Information Exchange Guidelines and Standards' 2023

[85] Barbara Glover and Nhlawulo Shikwambane, 'Pioneering Africa's AI Future: Convening of African AI Experts to Finalise the AU-AI Continental Strategy' August 7 2023 African Union Development Agency - NEPAD

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4. It is necessary to have a coherent, human-rights-centered policy for the ethical use of AI, robotics, and related technologies in healthcare in Africa. This policy should focus on the use of AI in assisted reproductive technology.
5. It is important to strengthen existing regulations on data governance as a first step towards AI regulation in Africa.

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